UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

CESAR CASTILLO, INC., individually and on behalf of all those similarly situated,

Plaintiff,

vs.

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA AMERICA HOLDINGS, INC., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA DEVELOPMENT CENTER AMERICAS, INC., MYLAN, INC., MYLAN PHARMACEUTICALS, INC., RANBAXY LABORATORIES, LTD., RANBAXY, INC., RANBAXY PHARMACEUTICALS, INC., SUN PHARMACEUTICAL INDUSTRIES LIMITED, ACTAVIS PLC, WATSON LABORATORIES, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., AND TEVA PHARMACEUTICALS USA, INC.,

Defendants.

15 CV 3505

Civil Action No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

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Plaintiff, CESAR CASTILLO, INC., files this civil antitrust action under Section 2 of the Sherman Act, Section 4 and 16 of the Clayton Act, New York's Donnelly Act, and Rule 23 of the Federal Rules of Civil Procedure, for treble damages, costs of suit, and other relief as maybe determined as just and proper, on behalf of itself and those similarly situated against Defendants Takeda Pharmaceutical Company Limited, Takeda America Holdings, Inc., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Development Center Americas, Inc. (collectively, "Takeda"), Mylan Inc. and Mylan Pharmaceuticals, Inc. (collectively, "Mylan"), Actavis plc f/k/a Actavis, Inc. and Watson Laboratories, Inc. (collectively, "Actavis"), Sun Pharmaceutical Industries Limited and Ranbaxy Laboratories, Ltd., Ranbaxy, Inc., and Ranbaxy Pharmaceuticals, Inc. (collectively, "Ranbaxy"), and Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (collectively, "Teva") (Mylan, Activis, Ranbaxy, and Teva, collectively, "Generic Defendants"), for Defendants' monopolization of the blockbuster oral Type 2 diabetes glycemic control medication "Actos" (pioglitazone hydrochloride) in the United States. Based upon personal knowledge, information, belief, and investigation of counsel, Plaintiff specifically alleges:

I. INTRODUCTION

1. Actos is a frequently-prescribed, orally administered glycemic control medication indicated to treat Type 2 diabetes.

2. At all relevant times, Actos was the only pioglitazone hydrochloride available in the marketplace (either as a stand-alone or as a combination therapy, as in Acto*plus* met), and as a result, Defendants exacted a supracompetitive price for and made supracompetitive profits on Actos sales. The amount of money motivating Defendants in this case is staggering: In 2011, Actos generated roughly $3 billion in annual sales in the United States alone. Defendants knew that these billions would essentially evaporate the moment generic Actos entered the market.

3. As alleged herein, Defendants sought to forestall entry of generic Actos and otherwise unlawfully extend their monopoly in the pioglitazone hydrochloride market through multiple, concerted, and deliberate anticompetitive acts, including, but not limited to (i) manipulation of the FDA's Orange Book regulations through listing of non-applicable patents, and (ii) use of "reverse payments" to delay market entry of any generic pioglitazone hydrochloride product from January 17, 2011 to, at least, August 17, 2012.

4. This suit is brought on behalf of Plaintiff and a proposed class that has purchased and continues to purchase pioglitazone hydrochloride products directly from Defendants at supracompetitive prices. Plaintiff and the class seek to hold Defendants accountable for their unlawful manipulation of FDA regulations and judicial processes in violation of the antitrust laws.

II. PARTIES

5. Plaintiff Cesar Castillo, Inc. ("CCI" or "Plaintiff") is a corporation organized under the laws of the Commonwealth of Puerto Rico, with its principal place of business located at Bo. Quebradas Arena, Rd. #1 Km. 26.0, Río Piedras, Puerto Rico, 00926. During the relevant period, CCI purchased pioglitazone hydrochloride products directly from Defendants at supracompetitive prices and suffered antitrust injury and damages as a result.

6. Defendant Takeda Pharmaceutical Company Limited is a Japanese company with its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645.

7. Defendant Takeda America Holdings, Inc. is a wholly-owned subsidiary of Defendant Takeda Pharmaceutical Company Limited, and is the United States parent corporation of Defendants Takeda Pharmaceuticals U.S.A., Inc. and Takeda Development Center Americas, Inc. Defendant Takeda America Holdings, Inc. is a corporation organized under the law of the

State of New York with its principal place of business at 767 Third Avenue, New York, New York 10017.

8. Defendant Takeda Pharmaceuticals U.S.A., Inc. (f/k/a Takeda Pharmaceuticals North America, Inc.) is a corporation organized under the laws of the State of Delaware with its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

9. Defendant Takeda Development Center Americas, Inc. (f/k/a Takeda Global Research and Development Center, Inc.) is a corporation organized under the laws of the State of Delaware with its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

10. Defendant Mylan, Inc. (f/k/a Mylan Laboratories, Inc.) is a corporation organized under the laws of the Commonwealth of Pennsylvania with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

11. Defendant Mylan Pharmaceuticals, Inc. is a corporation organized under the laws of the State of West Virginia with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

12. Defendant Ranbaxy Laboratories Limited ("Ranbaxy Labs") was a corporation that, until March 25, 2015, was organized and existed under the laws of India, with a principal place of business located at Plot 90, Sector 32, Gurgaon -122001 (Haryana), India. Ranbaxy Labs was the parent company to the entire Ranbaxy business empire, which was, until March 2015, the largest generic drug manufacturer in India. It controlled manufacturing, research, and development, as well as the conduct and functioning of its Indian-based facilities, including a facility located at Paonta Sahib, India.

13. Defendant Ranbaxy, Inc. is a corporation that is organized and exists under the laws of the State of Delaware, and has a place of business located at 600 College Road East,

Princeton, New Jersey, 08540. Ranbaxy, Inc.'s responsibilities include: (i) communications with the FDA on behalf of Ranbaxy Labs and its related entities; (ii) prosecution of ANDAs on behalf of Ranbaxy Labs; and (iii) management of U.S. litigation on behalf of Ranbaxy Labs and related entities. At all relevant times, Ranbaxy, Inc. acted in its own right and as an agent of Defendant Ranbaxy Labs.

14. Defendant Ranbaxy Pharmaceuticals, Inc. is a wholly-owned subsidiary of Defendant Ranbaxy, Inc., and is a corporation organized under the laws of the State of Delaware with its principal place of business at 600 College Road East, Suite 2100, Princeton, New Jersey 08540.

15. Defendant Sun Pharmaceutical Industries Limited ("Sun Pharma") is a public limited company incorporated under the laws of India with its registered office at Sun Pharma Advanced Research Centre (SPARC), Tandalja, Vadodara – 390 020, Gujarat, India and its corporate office is at Acme Plaza, Andheri Kurla Road, Andheri (East), Mumbai – 400 059, Maharashtra, India. Sun Pharma is an international, integrated, specialty pharmaceutical company. Pursuant to a Scheme of Arrangement between Ranbaxy Labs and Sun Pharm approved by the two companies' boards on April 6, 2014, and completed on or about March 25, 2015, Ranbaxy Labs merged into Sun Pharma, and all liabilities of Ranbaxy Labs, including contingent liabilities, have been transferred to and vested in Sun Pharm.

16. Defendant Actavis plc (f//k/a Actavis, Inc.) is incorporated under the laws of Ireland, with its principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland, and its United States place of business is Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. On or about October 1, 2013, Actavis, Inc. changed its name to Actavis plc, a year after Watson Pharmaceuticals, Inc. changed its name to Actavis, Inc.

as a result of Watson Pharmaceuticals, Inc.'s acquisition of Swiss-based Actavis Group in or around October 2012.

17. Defendant Watson Laboratories, Inc. was a Nevada corporation, having its principal place of business at 311 Bonnie Circle, Corona, California. Defendant Watson Laboratories, Inc. was a wholly-owned subsidiary of Watson Pharmaceuticals, Inc.

18. Defendant Teva Pharmaceutical Industries, Ltd., one of the largest pharmaceutical companies in the world, is headquartered in Petah Tikva, Israel.

19. Defendant Teva Pharmaceuticals USA, Inc. is an indirect, wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. Defendant Teva Pharmaceuticals USA, Inc. is a corporation organized under the laws of the State of Delaware with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

III. JURISDICTION AND VENUE

20. This action arises under Section 2 of the Sherman Act, 15 U.S.C. § 2, Section 4 of the Clayton Act, 15 U.S.C. § 15(a), and the Donnelly Act, New York Gen. Bus. Law § 340, *et seq.* and seeks to recover threefold damages, interest, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiff and Direct Purchaser Class members (defined below) resulting from Defendants' unlawful anticompetitive foreclosure of the United States market for pioglitazone hydrochloride products. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), 1367, and 1407, and 15 U.S.C. § 15.

21. Venue is proper in this district pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because during the Class Period (defined below), each Defendant resided, transacted business, was found, or had agents in this district, and a substantial portion of the alleged activity affected interstate trade and commerce discussed below has been carried out in this district.

22. Defendants' conduct, as described in this complaint, was within the flow of, was intended to have a substantial effect on, and did have a substantial effect on, the interstate commerce of the United States, including in this district.

23. During the class period, Defendants manufactured, sold, and shipped pioglitazone hydrochloride products in a continuous and uninterrupted flow of interstate commerce, which included sales of pioglitazone hydrochloride products in this district, advertisement of pioglitazone hydrochloride products in media in this district, monitoring prescriptions of pioglitazone hydrochloride products by prescribers within this district, and employment of product detailers in this district, who as agents of Defendants marketed pioglitazone hydrochloride to prescribers in this district. Defendants' conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce, including commerce within this district.

24. This Court has personal jurisdiction over each Defendant. Each Defendant throughout the United States and including in this district has transacted business, maintained substantial contacts, or committed overt acts in furtherance of the illegal scheme. The scheme has been directed at, and has had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

IV. CLASS ALLEGATIONS

25. Plaintiff, on behalf of itself and all other similarly situated direct purchaser class members, seeks damages, measured as overcharges, trebled, against Defendants based on allegations of anticompetitive conduct in the market for pioglitazone hydrochloride products and their AB-rated generic equivalents.

26. Plaintiff brings this action on behalf of itself and, under Fed. R. Civ. P. 23(a) and (b)(3), as a representative of a class of direct purchasers (the "Class" or "Direct Purchaser Class") defined as follows:

All persons or entities in the United States and its territories and possessions, including the Commonwealth of Puerto Rico, who purchased Actos or its AB-rated generic directly from any of the Defendants at any time during the period January 17, 2011 through and until the anticompetitive effects of the Defendants' conduct cease (the "Actos Class Period").

Excluded from the above-defined Direct Purchaser Classes are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

27. Members of the Direct Purchaser Class are so numerous that joinder is impracticable. Plaintiff believes that the Class numbers in the scores of entities. Further, the Direct Purchaser Class is readily identifiable from information and records in Defendants' possession.

28. Plaintiff's claims are typical of the Direct Purchaser Class claims. Plaintiff and all Class members were damaged by the same wrongful conduct of the Defendants – *i.e.*, they paid and will pay artificially inflated prices for Actos and its AB-rated generic equivalents, and were deprived of earlier and more robust competition from cheaper generic pioglitazone hydrochloride products as a result of the Defendants' wrongful conduct.

29. Plaintiff will fairly and adequately protect and represent the interests of the Direct Purchaser Class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the Direct Purchaser Class.

30. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products.

31. Questions of law and fact common to the members of the Direct Purchaser Class predominate over questions that may affect only individual Class members because the Defendants have acted on grounds generally applicable to the entire Direct Purchaser Class

thereby making overcharge damages with respect to the Direct Purchaser Class as a whole appropriate. Such generally applicable conduct is inherent in the Defendants' wrongful conduct.

32. Questions of law and fact common to the Direct Purchaser Class include, without limiation:

a. whether Defendants willfully obtained and/or maintained monopoly power over Actos and its AB-rated generic equivalents;

b. whether Defendants unlawfully excluded competitors and potential competitors from the market for Actos and its AB-rated generic equivalents;

c. whether Defendants unlawfully delayed or prevented generic manufacturers of pioglitazone hydrochloride products from coming to market in the United States;

d. whether Defendants maintained monopoly power;

e. whether the Defendants entered into an illegal contract, combination, conspiracy and/or other agreement in restraint of trade;

f. whether the law requires definition of a relevant market when direct proof of monopoly power is available, and, if so, the definition of the relevant market;

g. whether Defendants' activities as alleged herein have substantially affected interstate commerce;

h. whether, and, if so, to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiff and Class members; and

i. the quantum of aggregate overcharge damages to the Class.

33. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the

unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

34. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. REGULATORY BACKGROUND

35. Brand drug companies can, and do, obtain valid patents that cover their new prescription drug products. Such patents encourage discovery and development of new medicines, providing protection from competition by other drug companies for a length of time set under a statute by Congress.

36. Once the lawful periods of exclusivity expire on brand products, generic companies can seek FDA approval to sell generic versions of the brand, allowing the generic companies to manufacture generic products that are just as safe and effective, but far less expensive than the brand. The medication becomes affordable for all, and purchasers are no longer burdened by the high cost of the brand drug.

37. At root, then, is a basic principle in the American system of access to prescription drugs that addresses these goals and paves the way for both new and more affordable drugs. It is this: brand names have a statutory period of time to charge very high prices for medications that, in fact, cost little to manufacture, but it is a limited period, after which generic companies can compete with low-cost substitutes. And from this basic principle emerges a basic rule: that a drug companies should not deceive regulators and court officers to delay entry of less expensive, but therapeutically equivalent, generic medications.

A. The Competitive Effects of Generic Competition.

38. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective as their brand name counterparts. The only material difference between generic drugs and their corresponding brand name versions is their price. Because generic versions of a corresponding brand drug product are commodities that cannot be differentiated, the primary basis for generic competition is price. Typically, generics are at least 25% less expensive than their brand name counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic drug usually results in significant cost savings to all drug purchasers.

39. Since passage of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic equivalent hits the market, the generic quickly captures sales of the corresponding brand drug, often capturing 80% or more of the market within the first six months. This results in a loss of revenue for the brand drug company but dramatic savings for the American public. In a recent study, the Federal Trade Commission ("FTC") found that on average, within a year of generic entry, generics had captured 90% of corresponding brand drug sales and (with multiple generics on the market) prices had dropped 85%. As a result, competition from generic drugs is viewed by brand name drug companies, such as Takeda, as a grave threat to their bottom lines.

40. Generic competition enables all members of the proposed Class to: (i) purchase generic versions of the drug at substantially lower prices; and/or (ii) purchase the brand drug at a reduced price.

41. Until a generic version of the brand drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. Brand manufacturers, such as Takeda, are well aware of generics' rapid erosion of their brand sales. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible – including illegal means.

1. Prices drop upon entry of the first AB-rated generic.

42. Experience and economic research show that the first generic manufacturer to launch prices its product below the prices of its branded counterpart. Every state either requires or permits a prescription written for the brand drug to be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the branded form of the molecule. At the same time, there is a reduction in average price paid for a prescription for the molecule.

43. Pursuant to the Hatch-Waxman Amendments, the first generic manufacturer to file an abbreviated new drug application ("ANDA") containing a Paragraph IV certification receives 180 days of market exclusivity. This means that other generic manufacturers will not be able to launch their own generic products for at least six months after the first generic – known as the "first-filer" – launches its product.

44. During this 180-day exclusivity period, the first-filer is the only ANDA-approved generic manufacturer on the market. As recognized by the Supreme Court, it is often the case

that most of a first-filer's profits are earned during this 180-day exclusivity period. *FTC v. Actavis*, 133 S. Ct. 223, 229 (2013).

45. If the only versions of a drug on the market are the brand and the first filer's product, then the first filer prices its product below the brand product, but not as low as if it were facing competition from other generics. Since in these circumstances the first filer's product may compete only with the brand, and because the branded company rarely drops the brand price to match the first filer, the first filer does not face the kind of price competition it will when additional generic products are available.

2. Prices plummet when additional AB-rate generics enter the market.

46. When multiple generic competitors enter the market, competition accelerates and prices drop to their lowest levels. Multiple generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.

47. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates are that a single generic launch results in a near term retail price reduction of at least 10%, but that with two generic entrants near term retail price reduction is about 50%.

48. Soon after generic competition enters the market, the vast majority of the sales formerly enjoyed by the brand shift to the generic sellers. In the end, total payments to the brand manufacturer of the drug decline to a small fraction of the amounts paid prior to generic entry. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics.

B. The regulatory approval process for new branded drugs (NDAs).

49. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), drug companies who wish to sell a new drug product must file a New Drug Application ("NDA") with the FDA. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

50. The FDA may not approve an NDA if the data and test results provided fail to show that the drug is safe or if there is a lack of substantial evidence that the drug will be effective to treat the conditions suggested in the proposed labeling. The FDA approves new drugs based on their ability to satisfy the minimum regulatory requirements; namely, show that they are safe and effective to treat a particular indication. New drug applicants are not required to, and usually do not try to, show that their new drug product is better than other similar, already approved, products.

C. Brand companies may list NDA-applicable patents in the Orange Book.

51. To notify other drug manufacturers, a manufacturer of a new drug product must tell the FDA about patents that it believes cover its drug products. The FDA publishes a list of those patents in the publicly available "Orange Book." Patents issued after NDA approval may be listed in the Orange Book within 30 days of issuance. Once patents are listed in the Orange Book, potential generic competitors are on notice regarding the patents that are claimed to relate to the brand name drug.

52. The brand name drug manufacturer can list its patents in the Orange Book by filing a Form 3542 with the FDA. Under the FDA rules, the branded manufacturer is only permitted to list patents that are reasonably enforceable. Form 3542 expressly asks the applicant whether the drug presents a "No Relevant Patent" situation (*i.e.*, a situation where there are no patents that could be reasonably asserted in an infringement lawsuit). Form 3542 likewise

requires the signatory to affirm, under penalty of perjury, that all the patent information submitted to the FDA on each patent that claims the drug substance, drug product, or method of use that is the subject of the approved NDA or supplement is complete and accurate.

53. The FDA relies completely on the manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's representations. The FDA performs only a ministerial act in listing the patents identified by the manufacturer in the Orange Book.

D. The regulatory approval process for generic drugs (ANDAs).

1. Hatch-Waxman is designed to expedite introduction of generic drugs.

54. In 1984, Congress passed the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments were designed to speed the introduction of low-cost generic drugs to market by permitting generic manufacturers to file abbreviated new drug applications ("ANDAs") that rely on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, requiring only a showing that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand name drug. The premise – codified by Congress and implemented by the FDA for the past thirty years – is that two drug products that contain the same active pharmaceutical ingredient, in the same dose, delivered in the same way, and are absorbed into the blood stream at a similar rate over a similar period of time, are expected to be equally safe and effective.

55. At the same time, the Hatch-Waxman Amendments also sought to protect pharmaceutical companies' incentives to create new and innovative products, by, among other things, permitting a brand company to file a legitimate patent infringement lawsuit against a generic before the generic actually brought its product to market.

56. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historically high profit margins for brand name pharmaceutical companies. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion, with generic drugs accounting for 18.6% of prescriptions. By 2013, total prescription drug revenue had soared to over $329 billion, with generic drugs accounting for 84% of prescriptions.

2. Hatch-Waxman permits generics to challenge questionable patents before launch.

57. The Hatch-Waxman Amendments also created a mechanism to resolve patent disputes between brand and generic manufacturers before generic products launched, in the hopes of resolving patent challenges in advance of the generic launch (so that the generic's launch will not be unnecessarily delayed while patent squabbles ensue). The Amendments permitted a brand manufacturer to sue a generic for patent infringement even if their products had not launched yet.

58. Once one or more patents are listed in the Orange Book, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any of those patents to obtain FDA approval of an ANDA. A generic manufacturer can make one of four certifications:

i. that no patent for the brand name drug has been filed with the FDA;

ii. that the patent for the brand name drug has expired;

iii. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date; or

iv. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product.

59. If a generic manufacturer files a Paragraph IV certification, a brand name manufacturer can sue the ANDA applicant for patent infringement. If the brand name manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the entry of a final judgment on a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA cannot authorize the generic manufacturer to go to market with its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

60. The brand could file patent infringement claims more than 45 days after receiving the Paragraph IV certification, but doing so would not trigger the automatic stay of FDA approval.

VI. FACTUAL ALLEGATIONS

A. In 1987, the PTO issued the '777 compound patent covering Actos; in 1999, the FDA approved Takeda's application to market Actos in the United States.

61. On August 18, 1987, the United States Patent and Trade Office (the "PTO") issued to inventors Kanji Meguro and Takeshi Fujita U.S. Patent No. 4,687,777 entitled "Thiazolidinedione Derivatives, Useful As Antidiabetic Agents" (the "'777 Compound Patent"). This patent was at first assigned to Takeda Chemical Industries, Ltd., and then later to another Takeda entity. The '777 Compound Patent purports to claim the novel compound commonly known under the nonproprietary name "pioglitazone" and its pharmacologically acceptable salts including pioglitazone hydrochloride, the active ingredient for Actos. Because Actos and its combination product, Acto*plus* met, use the same active pharmaceutical ingredient

(pioglitazone), each of those products are covered by the '777 Compound Patent. After accounting for applicable extensions, the '777 Compound Patent was set to expire on January 17, 2011.

62. On January 15, 1999, Takeda submitted NDA 021073 to the FDA, seeking approval to manufacture, market, and sell Actos.

63. On July 15, 1999, the FDA approved Takeda's NDA for the use of Actos to improve glycemic control in adults with Type 2 diabetes – either as monotherapy or in combination with a sulfonylurea, metformin, or insulin.

64. As permitted by the FDCA and applicable regulations, Takeda submitted the '777 Compound Patent for listing in the Orange Book as a drug substance patent covering Actos.

65. Following the FDA's July 15, 1999 approval, Takeda began marketing Actos in the United States.

66. At the time of Actos' launch, the FDA had determined, at Takeda's request, that the NDA for Actos tablets (NDA 021073) had a new chemical entity ("NCE"). As such, Takeda was entitled to NCE exclusivity that prevented the submission of an ANDA until expiration of five years from NDA approval (which, for Actos, meant NCE exclusivity expired on July 15, 2004). However, if an ANDA applicant certified that one or more of the patents listed for the reference listed drug ("RLD") was invalid or not infringed (*i.e.*, files a Paragraph IV certification), then an ANDA may be submitted a year earlier. *See* 21 U.S.C. § 355(j)(5)(F)(ii).

67. In short, when the FDA approved Actos in July of 1999, Takeda knew that: (i) it had NCE exclusivity such that the first ANDAs could be filed as early as July 15, 2003, and (ii) its '777 Compound Patent for the active pharmaceutical ingredient pioglitazone extended until January 17, 2011. This meant that after July 15, 2003, Takeda would have no legitimate,

practical basis to exclude competition beyond the expiration of the '777 Compound Patent on January 17, 2011. Takeda also knew that, whether before or after expiration of the '777 Compound Patent, the market entry of a generic would likely mean the near complete loss of Actos sales.

B. Takeda Wrongfully List the '584 and '404 Insulin Patents in the Orange Book.

68. During the 1990s, Takeda employees explored ways to develop products that were to be used in combination with pioglitazone, as a means to extend Actos' market exclusivity.

69. On October 12, 1999, the PTO issued United States Patent Nos. 5,965,584 (the "'584 Combo Patent") entitled "Pharmaceutical Composition." This patent was assigned to Takeda Chemical Industries, Ltd. and later to a different Takeda entity. The '594 Combo Patent purports to claim a pharmaceutical composition comprising pioglitazone or salts thereof *in combination with* a biguanide (*e.g.*, metformin) and methods for treating diabetes which comprise administering a therapeutically effective amount of pioglitazone or salts thereof *in combination with a biguanide* (*e.g.*, metformin). The '584 Combo Patent expires on June 19, 2016.

70. The '584 Combo Patent does not claim the compound pioglitazone (the active Actos drug ingredient). At most, the '584 Combo Patent claims a method of using pioglitazone in combination with another active ingredient, such as metformin. As a result, the '584 Combo Patent does not conceivably cover a standalone pioglitazone drug product, and thus would not cover Actos. Takeda knew this. The '584 Combo Patent only potentially covers a combination product using both those ingredients -- i.e., what eventually would be sold by Takeda as the purported commercial embodiment of the '584 Combo Patent: Acto*plus* met.

71. On or about November 5, 1999 – and despite knowing its newly acquired '584 Combo Patent in no legitimate way could be read to cover Actos, but aware that sales from its promising new Actos franchise would likely be wiped out by generic entry upon the expiration of the '777 Compound Patent – Takeda filed information with the FDA stating that the '584 Combo Patent claimed both the "drug product" Actos and its "method of use." Takeda thus caused the '584 Combo Patent to be listed in the Orange Book as covering Actos. In doing so, Takeda knowingly and falsely submitted patent information to the FDA describing the '584 Combo Patent as a drug product patent that claims Actos. When submitting the '584 Combo Patent information to the FDA, Takeda knew that the information was false and misleading. Takeda acted with the purpose and effect of impairing competition from generics, and it did so for the specific purpose of seeking to extend its Actos monopoly beyond January 17, 2011.

72. On December 11, 2001, the PTO issued U.S. patent No. 6,329,404 (the "'404 Insulin Patent") entitled "Pharmaceutical Composition." This patent was assigned to Takeda Chemical Industries, Ltd. and later to a different Takeda entity. The '404 Insulin Patent purports to claim a pharmaceutical composition comprising pioglitazone or salts thereof *in combination with* an insulin secretion enhancer (*e.g.*, a sulfonylurea, such as glimepiride) and methods for treating diabetes which comprise administering a therapeutically effective amount of pioglitazone or salts thereof in combination with an insulin secretion enhancer. The '404 Insulin Patent expires on June 19, 2016.

73. The '404 Insulin Patent did not claim the compound pioglitazone (the active pharmacological ingredient in Actos); at most, the '404 Insulin Patent claims a method of using pioglitazone in combination with an insulin secretion enhancer active ingrediant (*e.g.*, a sulfonylurea, such as glimepiride). As a result, the '404 Insulin Patent does not conceivably

cover a standalone pioglitazone drug product, and thus would not cover Actos (or Actoplus met for that matter). Takeda knew this. The '404 Insulin Patent only potentially covers a combination product using both pioglitazone and an insulin secretion enhancer. As such, the '404 Insulin Patent arguably covers what eventually would be sold as Duetact (not at-issue here).

74. On or about January 3, 2002 – and despite knowing that its newly acquired '404 Insulin Patent could in no legitimate way be read to cover Actos, but aware that its booming Actos franchise sales would likely be wiped out by generic entry upon the expiration of the '777 Compound Patent in January 2011– Takeda submitted patent information with the FDA stating that the '404 Insulin Patent claimed both the "Drug Product" Actos and its "Method of Use." Takeda thereby caused the '404 Insulin Patent to be listed in the Orange Book as covering Actos. In doing so, Takeda knowingly and falsely submitted patent information to the FDA describing the '404 Insulin Patent as a drug product patent that claims Actos. Takeda acted with the purpose and effect of impairing competition from generic, and it did so for the specific purpose of seeking to extend its monopoly beyond January 17, 2011.

75. In addition to the '777 Compound Patent, the '584 Combo Patent, and the '404 Insulin Patent, Takeda submitted eight other patents to the FDA for listing in the Orange Book::

Patent No.	Issue Date	Patent Expiry
6,150,383 (the "'383 Patent")	November 21, 2000	June 19, 2016
6,150,384 (the "'384 Patent")	November 21, 2000	June 19, 2016
6,166,042 (the "'042 Patent")	December 26, 2000	June 19, 2016
6,166,043 (the "'043 Patent")	December 26, 2000	June 19, 2016
6,172,090 (the "'090 Patent")	January 9, 2001	June 19, 2016
6,211,205 (the "'205 Patent")	April 3, 2001	June 19, 2016
6,271,243 (the "'243 Patent")	August 7, 2001	June 19, 2016
6,303,640 (the "'640 Patent")	October 16, 2001	August 9, 2016

These patents (the "Actos Method-of-Use Patents") claimed various methods of using Actos in

combination with other drug products (such as biguanide or an insulin secretion enhancer) to treat various conditions or to reduce various side effects. Takeda listed the Actos Method-of-Use Patents in the Orange Book sole as method of use patents, not drug substance or drug product patents.

76. Under both the Hatch-Waxman Act and the FDA's implementing regulations, the drug product claims of the '584 Combo Patent and the '404 Insulin Patent do not form a permissible basis for Takeda to submit patent information describing the patents as drug product patents covering Actos.

77. Takeda could properly identify the '584 Combo Patent and the '404 Insulin Patent as drug product patents claiming Actos only if the patents in fact claimed the Actos drug product. The patents unequivocally do not do so. The *only* active ingredient in Actos is pioglitazone hydrochloride. By contrast, the drug product claims in the '584 Combo Patent and the '404 Insulin Patent claim drug products containing *both* pioglitazone *and* certain additional active ingredients—biguanide or an insulin secretion enhancer, respectively. Neither patent claims a drug product that contains pioglitazone as its sole active ingredient. Thus, the patents do not claim the Actos drug product as a matter of law.

78. Takeda could not reasonably assert the drug product claims of the '584 Combo Patent or the '404 Insulin Patent against ANDA manufacturers seeking to market generic Actos. The patents claimed only drugs *other* than the Actos drug product. In fact, it would be impossible for any ANDA referencing the Acots NDA to get FDA approval of a drug containing either of the compositions claimed in the '584 Combo Patent and '404 Insulin Patent. (In patent litigation to be described below, Takeda would eventually concede the inapplicability of the

'584 Combo Patent and the '404 Insulin Patent for Actos generics when it withdrew the infringement claims based on those patents).

79. Takeda's wrongful listing of the '584 Combo Patent and the '404 Insulin Patent in the Orange Book as covering Actos had several effects on the regulatory paths available for generic entry.

80. First, a would-be maker for generic Actos might see itself as needing to file a certification of some sort with respect to those patents (*e.g.*, a Paragraph IV certification that the patents were invalid, unenforceable or not infringed, or some other form of certification).

81. Second, if a Paragraph IV certification were made, Takeda would be able to file an infringement lawsuit based on the technical act of infringement, and a would-be generic maker proceeding by way of a Paragraph IV certification would (if timely sued by Takeda for infringement) be blocked from FDA approval by the automatic 30-month stay. Third, the fact that the patents had been listed in the Orange Book meant that the *first* generic applicant(s) to file an ANDA would gain the 180-day exclusivity for ANDA-approved generics. In effect, the wrongful listing of the '584 and '404 created an opportunity for one (or more) first-filer generics to enjoy a 180-day exclusivity right (and ability to bottleneck competitors' applications) for Actos that otherwise would not have existed.

C. The first Actos ANDAs.

82. Generic drug manufacturers were eager to apply for FDA approval to market generic versions of Actos.

83. On July 15, 2003 – the first day generics could do so given the NCE status of Actos – four generic manufacturers, Mylan, Alphapharm (which Mylan subsequently acquired), Ranbaxy, and Actavis, each filed an ANDA seeking FDA approval to manufacture, market, and sell generic Actos.

84. The Mylan ANDA (ANDA No. 076801), contained a Paragraph IV certification as to the '777 Compound, the '584 Combo, and the '404 Insulin Patents, and Section viii statements as to the Actos Method-of-Use Patents.

85. By letter dated September 8, 2003, Mylan notified Takeda that Mylan had filed ANDA No. 076801 seeking to manufacture, market, and sell a generic version of Actos and that the ANDA contained a Paragraph IV certification as to the '777 Compound, the '584 Combo, and the '404 Insulin Patents, and Section viii statements as to the Actos Method-of-Use Patents.

86. As accepted for filing by the FDA, the Actavis ANDA (ANDA No. 076798), contained a Paragraph III certification as to the '777 Compound Patent, a Paragraph IV certification as to the '584 Combo and '404 Insulin Patents, and Section viii statements as to the Actos Method-of-Use Patents.

87. By letter dated September 9, 2003, Actavis notified Takeda that Actavis had filed ANDA No. 076798 seeking to manufacture, market, and sell a generic version of Actos and that the ANDA contained a Paragraph III certification as to the '777 Compound Patent, a Paragraph IV certification as to the '584 Combo and '404 Insulin Patents, and Section viii statements as to the Actos Method-of-Use Patents.

88. The Ranbaxy ANDA (ANDA No. 076800), contained a Paragraph III certification as to the '777 Compound Patent, a Paragraph IV certification as to the '584 Combo and '404 Insulin Patents, and Section viii statements as to the Actos Method-of-Use Patents.

89. By letter dated September 18, 2003, Ranbaxy notified Takeda that Ranbaxy had filed ANDA No. 076800 seeking to manufacture, market, and sell a generic version of Actos and that the ANDA contained a Paragraph III certification as to the '777 Compound Patent, a

Paragraph IV certification as to the '584 Combo and '404 Insulin Patents, and Section viii statements as to the Actos Method-of-Use Patents.

90. As a result of these filings, each of the first wave generics – Mylan, Ranbaxy, and Actavis – chose to address the impediments presented by the Orange Book listings of the '584 Combo Patent and the '404 Insulin Patent by submitting Paragraph IV certifications as to those patents. By doing so, each took advantage of the opportunity that should not have existed by reason of Takeda's wrongful listing of those patents – the chance to be treated as "first-to-file" ANDA applicants entitled to enjoy 180-day exclusivity from other generic company ANDA-approved sales, and the ability to bottleneck the entry of other generics (subject to certain exceptions, which will be addressed later) until such time as one of these first wave filers chose to launch its generic. The FDA ultimately concluded that Mylan, Ranbaxy, and Actavis were entitled to "shared" 180-day exclusivity with respect to generic Actos; each had first-to-file exclusivity (subject to exceptions) from non-first wave generic makers for the first six months from when the first of any one of the first wave filers chose to launch their generic product (assuming the company had final approval from the FDA, of course).

91. On October 17, 2003, Takeda filed three separate suits in the United States District Court for the Southern District of New York: *Takeda Chemical Industries, Ltd, et al. v. Ranbaxy Laboratories, Ltd, et al.*, Civil Action No. 1:03-cv-08250-DLC (S.D.N.Y.); *Takeda Chemical Industries, Ltd., et al. v. Mylan Laboratories Inc., et al.*, Civil Action No. 1:03-cv-08253-DLC (S.D.N.Y.); and *Takeda Chemical Industries, Ltd, et al. v. Watson Pharmaceuticals, Inc., et al.*, Civil Action No. 1:03-cv-08254-DLC (S.D.N.Y.). Takeda alleged that Ranbaxy's, Mylan's and Actavis' generic Actos products would infringe the drug product claims of the '584 Combo and and '404 Insulin Patents, pursuant to 35 USC § 271(e)(2)(A), and induce

infringement of the method-of-use claims of the '584 Combo and '404 Insulin Patents and certain of the Actos Method-of-Use Patents, pursuant to 35 USC § 271(b). Takeda also alleged that Mylan's generic Actos product would infringe the '777 Compound Patent, pursuant to 35 USC § 271(e)(2)(A). Takeda filed the patent infringement cases against Mylan, Actavis, and Ranbaxy without regard to the merits of the cases with respect to the '584 Combo and '404 Insulin Patents.

92. During the litigation, Mylan, Actavis, and Ranbaxy secured substantial evidence via discovery supporting a host of defenses focusing on: (i) the enforceability of the '584 Combo and '404 Insulin Patents; (ii) the validity of the '584 Combo and the '404 Insulin Patents; and (iii) the strength of Takeda's infringement allegations regarding the '584 Combo, '404 Insulin, and the Actos Method-of-Use Patents. Indeed, before the scheduled trial in June 2010 with respect to the '584 Combo and '404 Insulin Patents, Takeda withdrew its allegations that Mylan, Actavis, and Ranbaxy's generic Actos products infringed the drug product claims of the '584 Combo and '404 Insulin Patents.

93. To prevent generic entry using just the strength of its the '584 Combo Patent, the '404 Insulin Patent and the Actos Method-of-Use Patents, Takeda would have had to defeat each of Mylan's, Ranbaxy's, and Actavis' arguments regarding direct and indirect infringement of those patents. Takeda instead would later decide to protect its monopoly by paying Mylan, Ranbaxy, and Actavis to withdraw their defenses to those patents and delay introducing their generic Actos products.

D. The Teva Actos ANDA.

94. In the 2000s, Israel-based Teva had grown to become one of the world's largest drug makers, focusing on finished generic products.

95. On or around July 14, 2004, Teva filed ANDA No. 077210, seeking tomanufacture, market and sell generic Actos.

96. The Teva ANDA contained a Paragraph III certification as to the '777 Compound Patent, which meant Teva would not seek to market its generic product before the January 17, 2011 expiration of that patent. Teva refused, however, to submit a Paragraph IV certification with respect to either the '584 Combo Patent or the '404 Insulin Patent. Instead, with respect to those patents, as well as the Method-of-Use Patents, Teva included only Section viii statements. As permitted by applicable regulations, the Section viii statements asserted that Teva's label for its generic Actos would "carve out" information regarding methods of using Actos in combination with a biguanide or an insulin secretion enhancer (the methods of use claimed by the '584 Combo Patent and '404 Insulin Patent, respectively) or other uses covered by the Method-of-Use Patents.

97. Teva's decision not to include a Paragraph IV certification with respect to the '584 Combo and '404 Insulin Patents raised the possibility that the FDA could approve Teva's ANDA without regard to whether any other ANDA applicant was otherwise entitled to a 180-day exclusivity period with respect to Actos. In other words, Teva's Section viii strategy set up the real potential for Teva to leap frog over the first-wave of generic Actos filers (Mylan, Ranbaxy, and Actavis) and launch a generic Actos once the '777 Compound Patent expired in January 2011.

98. Because the Teva ANDA did not contain a Paragraph IV certification with respect to any Orange Book-listed patent for Actos, Teva was not required to, and so did not, send notice to Takeda regarding the Teva ANDA.

E. The '777 Compound Patent Trial.

99. Following discovery, the Takeda actions against Mylan, Ranbaxy, and Actavis were consolidated. The Court hearing the consolidated action opted to try Mylan's challenge to the '777 Compound Patent before considering the other asserted patents.

100. After a bench trial held in January 2006, the Court found that the '777 Compound Patent was not invalid due to obviousness and that Takeda had not engaged in inequitable conduct in obtaining the patent. *Takeda Chem. Indus., Inc. v. Mylan Labs., Inc.*, 417 F. Supp. 2d 341 (S.D.N.Y. 2006). This decision was upheld on appeal. *Takeda Chem. Indus., Inc. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007).

101. The decisions on the '777 Compound Patent had no bearing on the merits of Takeda's infringement claims based on the '584 Combo and '404 Insulin Patents, nor did it have any bearing on whether Takeda had wrongfully listed those patents in the Orange Book.

F. Other generic manufacturers file ANDAs for generic Actos.

102. While the Takeda litigation against Mylan, Actavis, Ranbaxy, and Teva regarding their ANDAs for Actos continued, other generics filed ANDAs for generic Actos that contained Paragraph IV certifications as to some or all of the Orange Book-listed patents for Actos. These generics notified Takeda of their respective ANDAs and the Paragraph IV certifications contained therein, and Takeda filed suit against each of these generics, alleging infringement of the '584 Combo Patent, the '404 Insulin Patent, and certain of the ACTOS Method-of-Use Patents:

Generic	ANDA No.	Date Sued
Sandoz, Inc.	078670	May 16, 2007
Torrent Pharmaceuticals Ltd.	091298	July 22, 2009
Aurobindo Pharma Ltd.	200268	January 13, 2010

Dr. Reddy's Laboratories Ltd.	078383	May 20, 2010
Wockhardt Ltd.	078038	July 28, 2010
Synthon Pharmaceuticals, Inc.	078472	September 8, 2010
Zydus Pharmaceuticals USA, Inc.	202456	January 14, 2011
Apotex, Inc.	202502	March 4, 2011
Macleods Pharmaceuticals Ltd.	202467	May 6, 2011
Accord Healthcare, Inc.	200044	September 12, 2011
Hetero Drugs Ltd.	293467	November 16, 2011

G. Takeda wrongfully maintains its '584 and '404 Orange Book listings for Actos.

103. Since Takeda first listed the '584 Combo and the '404 Insulin Patents in the Orange Book back in October 1999 and January 2002, respectively, Takeda wrongfully used those listings over the years, and it repeatedly reiterated its untruthful position that those patents cover generic Actos products.

104. For example, Takeda had used the wrongful listings to force Paragraph IV certifications by the first-wave generic Actos filers, had filed lawsuits against the first-wave filers alleging infringement of the '584 Combo and the '404 Insulin Patents when neither patent claimed Actos, and forced Teva to respond to those listing with an alternative approach (it chose a Section viii approach).

105. On or about January 22, 2010 (and continuing its conduct of using the wrongful listings to gain anticompetitive advantage), Takeda responded to a citizen petition ("CP") submitted to the FDA by Sandoz, another generic Actos ANDA filer. That CP asserted that Takeda had improperly caused the FDA to list the '584 Combo and '404 Insulin Patents in the Orange Book as drug product patents for Actos. In its Comment to the Citizens Petition, dated January 22, 2010, Takeda "confirm[ed] for FDA the listing of [the '584 Combo Patent and '404

Insulin Patent] under the terms described in Takeda's original patent submissions." Takeda further acknowledged that it "characterized them for FDA in the appropriate patent declarations as containing both 'Drug product' and 'Method of use' claims," and that "[s]ince the original submission of these patents to FDA, Takeda has continued to certify to the applicability of the patents to ACTOS under the original declarations."

106. In its March 15, 2010 ruling on the CP, the FDA confirmed that Takeda's original patent information had indeed "stated that the patents claimed both the drug product and a method of use." The FDA further concluded that "[i]n keeping with our practice of relying solely on the NDA sponsor's patent declaration describing relevant patent claims in Orange Book-listed patents, FDA will rely on Takeda's patent declarations submitted to FDA." The FDA specifically noted that Takeda's January 22, 2010 CP comment had "reconfirm[ed]" the original listing. Moreover, "FDA's role in listing patents and patent information in the Orange Book is ministerial," and "FDA relies on the NDA sponsors to provide an accurate patent submission."

107. The FDA concluded that, because Takeda had submitted patent information describing the '584 Combo and '404 Insulin Patents as claiming the Actos drug product, all ANDA filers seeking approval to market generic Actos before the expiration of the patents were required to submit Paragraph IV certifications, rather than Section viii statements, with respect to them. The requirement that Teva and all ANDA filers submit Paragraph IV certification – and thereby become subject to the first-filer's 180-exclusivity – resulted from Takeda's description of the '584 Combo and '404 Insulin Patents as drug product patents claiming Actos (notwithstanding that neither patent in fact claimed Actos). The FDA concluded that, "it is the patent declaration submitted by the NDA holder and any subsequent amendments or supplements to that declaration that controls FDA's listing of patents and patent information. In

keeping with our practice of relying solely on the NDA sponsor's patent declaration describing relevant patent claims in Orange Book-listed patents, FDA will rely on Takeda's patent declarations submitted to FDA."

108. The Teva litigation was scheduled for trial beginning in June 2010, in time for Teva to obtain a favorable ruling before the expiration of the '777 Compound Patent in January 2011.

109. On March 15, 2010, while the lawsuit was pending, the FDA issued its decision on the CP discussed above, concluding that, in its purely ministerial role, the FDA would rely solely on Takeda's patent information. Because Takeda submitted patent information stating that the '584 Combo and '404 Insulin Patents claimed both the "drug product" Actos and its "method of use," the FDA concluded that it could not approve any ANDA that did not include a Paragraph IV certification as to the '584 Combo and '404 Insulin Patents, which Teva's Actos ANDA did not include.

H. Early 2010 Actos competition dynamics.

110. In early 2010, Takeda, the first-wave generics (Mylan, Ranbaxy, and Actavis), and Teva each faced competitive pressures produced by our free market system, the structure of competition established by the Hatch-Waxman Act, and laws fostering automatic substitution of brand drugs by FDA-approved generic equivalents upon expiry of valid patents.

111. As to Takeda, it was enjoying a $3 billion a year Actos franchise, but time was quickly running out. By January, 17, 2011, the day the '777 Compound PAtent was set to expire, Takeda would face generic challenges not only from the first-wave generics and Teva, but also from over a half dozen other generics that were actively seeking FDA approval for generic Actos. Takeda knew that once a generic Actos entered the market, its billions in Actos sales would evaporate almost overnight.

112. For Mylan and its Actos ANDA, Mylan faced competition on numerous fronts. First, Mylan faced competition from the two other generic manufacturers (Actavis and Ranbaxy) with whom it shared the first-to-file 180-day exclusivity for Actos. Since both of those companies had pending ANDAs, either one or the other might seek to obtain FDA approval and launch its product as close to January 17, 2011 as possible. Once launched, the 180-day exclusivity period would be triggered, and Mylan (and the other first-filers) would need to have obtained its FDA approval to launch in order to enjoy as much of that now-triggered 180-day exclusivity period as possible. Second, Mylan faced competition from Teva (the largest generic manufacturer) which at the time was pursuing a separate, rapid regulatory approach (the Section viii approach) to gain FDA approval to launch generic Actos ahead of the first-filers. If Teva were able to get a favorable ruling (from the FDA or a court) on its Section viii position during 2010 or so (a highly likely prospect given the clear lack of coverage of the '584 Combo and '404 Insulin Patents), then Teva would be able to immediately enter the market, and Mylan would lose the substantial economic benefit from its 180-day exclusivity. Third, Mylan faced likely competition from Takeda because, upon generic entry and regardless of the 180-day exclusivity, Takeda would be able to launch an authorized generic product at any time, and thereby further reduce Mylan's market share and force further price pressure downwards. Fourth, Mylan faced competition from numerous other generic companies because, upon lapse of the 180-day exclusivity, the Actos market would likely become inundated with multiple generic makers such that the entire Actos market would become wholly commoditized.

113. Mylan's *lawful* settlement option was to resolve the Actos litigation with Takeda, but to do so separately from its generic competitors, without accepting a payoff from Takeda, and without colluding with Takeda and the other two first wave generics to set future entry

dates (or prices). Acting in its own, independent economic interest (and without colluding with its competitors), Mylan would seek an agreed entry date on or about January 17, 2011; after all, if Mylan accepted any later date, it would be exposed to the potential that one of its competitors would obtain an earlier entry date (by settlement or litigation). As a result, it was in Mylan's own, independent economic interest (without colluding with its competitors) to seek an agreement for entry on or about January 17, 2011. Absent that, Mylan would press litigation, and likely win it.

114. As for Actavis and Ranbaxy and their Actos ANDAs, they were in a similar position as Mylan. Each faced competition from the other generics with whom they shared 180-day exclusivity, faced the threats of Takeda's authorized generic, and faced Teva's early entry generic threat (through its Section viii approach), and faced the prospect of complete commoditization upon expiration of the 180-day exclusivity (or Teva's success with its Section viii approach). Acting in their own, independent economic interest (and without colluding with their competitors), Actavis and Ranbaxy would each (separately) seek from Takeda an agreed entry date on or about January 17, 2011; were either to agree to any later date, it would be exposed to the potential that one of its competitors would obtain an earlier entry date (by settlement or litigation). Absent an agreement for entry on or about January 17, 2011, they would press litigation, and win it.

115. And finally, Teva faced significant competitive pressures, but also had some advantages. As to Teva's Actos ANDA, while Teva knew that other generic companies had a shared 180-day exclusivity, it also knew it was pursuing generic Actos FDA approval through a Section viii approach, and that doing so was likely to avoid the lengthy tedium of the Paragraph IV certification process. And since Teva's approach would vitiate the 180-day stranglehold,

Teva had strong economic incentive to pursue that approach and gain a period of *de facto* exclusivity for itself. In short, in early 2010 Teva was very much in a spoiler role, asserting significant pressure to gain timely generic entry.

I. Takeda's group deal with the first-wave generics: Mylan, Ranbaxy, and Actavis.

116. In late February and early March of 2010, Takeda orchestrated a group deal with Mylan, Ranbaxy, and Actavis in order to delay generic entry. Rather than pursue their independent economic interests, all four companies agreed to an overarching scheme to restrain the competitive pressures they faced. They combined their efforts, and reached an overall agreement to (i) allocate the Actos markets, (ii) set uniform agreed entry dates between themselves, (iii) delay the entry of generics, (iv) collude to protect their first-filer 180-day exclusivity obtained through Takeda's wrongful Orange Book listings, and (v) restrain Teva's effort to gain timely entry of generic Actos. The overall agreement was in reality a single deal between all four companies, but they memorialized the agreement in separate written agreements between the companies, though the documents contained nearly identical entry date provisions and disincentives for independent actions. In purpose and effect, the first-wave generics – Mylan, Ranbaxy, and Actavis – joined Takeda's long-term scheme to delay generic competition. The overall, single agreement is herein called the Exclusion Payment Agreement.

117. On or about March 15, 2010, Takeda entered into the Exclusion Payment Agreement with each of Mylan, Ranbaxy, and Actavis. For Actos, the Exclusion Payment Agreement required Takeda to immediately dismiss its patent infringement litigation against Mylan, Ranbaxy, and Actavis, and for Mylan, Ranbaxy, and Actavis to drop their Actos patent challenges. Mylan, Ranbaxy, and Actavis also agreed to delay launching their generic Actos products until August 17, 2012, or earlier under certain circumstances.

118. As the *quid pro quo* for Mylan's, Ranbaxy's, and Actavis' agreements to drop their challenges to the patents and delay market entry for generic Actos, Takeda agreed to pay Mylan, Ranbaxy, and Actavis substantial sums. Takeda's payments to the first-wave Generic Defendants under the Exclusion Payment Agreement took several forms.

119. Takeda agreed that in the event any other generic Actos product entered the market before August 17, 2012, the licensed entry dates for Mylan, Ranbaxy, and Actavis would be moved up accordingly. The purpose and effect of these acceleration clauses was to deter any other generic drug manufacturer from entering the market before then, and serve as an invitation to join the scheme. In particular, Takeda, Mylan, Ranbaxy, and Actavis specifically intended these clauses to create a major disincentive for Teva to continue its effort to gain timely generic entry through its Section viii approach; the agreement also sought to incentivize Teva to join the agreement to delay generic Actos entry until August 17, 2012. Eliminating the potential for Teva to enter the market before Mylan, Ranbaxy, and Actavis was of enormous benefit to the generics – worth hundreds of millions of dollars – and was compensation that they could not have obtained even if they had won the Actos patent litigation. The acceleration clauses were large and unjustified payments from Takeda to each of Mylan, Ranbaxy, and Actavis.

120. As to Mylan, Takeda agreed to safeguard Mylan's first-filer 180-day exclusivity period for Acto*plus* met, by inclusion of a similar acceleration clause. This acceleration clause safeguarding Mylan's first-filer status had significant commercial value, and represented a large and unjustified payment, to Mylan.

121. As to Ranbaxy, Takeda agreed to two "sweetheart" deals. For the Actos sweetheart deal, Takeda gave Ranbaxy the right to enter with an authorized generic Actos under distribution terms that provided Ranbaxy with net revenue far in excess of fair market terms.

But in order to induce Ranbaxy to delay entry with its generic Actos, Takeda gave Ranbaxy a license for Acto*plus* met that was of substantial value to Ranbaxy and was compensation that it could not have been obtained even if it had won the Actos patent litigation. The license for Acto*plus* met was a large and unjustified payment from Takeda to Ranbaxy.

122. As to Actavis, Takeda provided another "sweetheart" deal. Actavis had not filed an ANDA seeking FDA approval to market Acto*plus* met and had not made any certifications that Takeda's patents on Acto*plus* met were invalid or would not be infringed by a generic version of Acto*plus* met. But in order to induce Actavis to delay entry with its generic Actos, Takeda gave Actavis a license for Acto*plus* met that was of substantial value to Actavis and was compensation that it could not have been obtained even if it had won the Actos patent litigation. The license for Acto*plus* met was a large and unjustified payment from Takeda to Ranbaxy.

123. All of these benefits had substantial value to Mylan, Ranbaxy, and Actavis, and are compensation that they could not have otherwise obtained even if they had litigated and won the various patent cases. These payments caused Mylan, Ranbaxy, and Actavis to stay out of the markets for Actos longer than they otherwise would have. And Takeda made these payments to Mylan, Ranbaxy, and Actavis in exchange for their agreeing to delay entry with their generic Actos products. In short, Takeda made large, unjustified payments to Mylan, Ranbaxy, and Actavis to delay their entry into the market with generic Actos.

J. The Exclusion Payment Agreement had its intended anticompetitive effect.

124. The Exclusion Payment Agreement was intended to restrict competition in the Actos market in multiple ways, and the restrictions impacted each competitive threat that would have otherwise existed.

125. *First*, the arrangement restricted the competition that previously existed between Mylan, Ranbaxy, and Actavis, each of which was supposed to be competing with the others to

gain the earliest possible entry date. Since they orchestrated a mutually agreed entry date amongst themselves, none now faced any threat that one or both of the two others would beat them to market and gain an advantage of enjoying more of the 180-day shared exclusivity period. Thus, the natural economic motivation of each to obtain an earlier entry date than the others was eliminated.

126. *Second*, the arrangement restricted competition by significantly reducing the incentives for Teva to continue its Section viii efforts to gain timely generic entry. Because Takeda had arranged that all three first-wave generic filers could enter the market if Teva succeeded in its Section viii approach to timely generic entry, Teva knew that it no longer had a reasonable prospect of gaining timely entry with *de facto* exclusivity for some period of time; instead, the other generics could also pounce into the market at that time too.

127. *Third*, the arrangement restricted competition by helping to maintain the 180-day exclusivity held by Mylan, Ranbaxy, and Actavis for Actos. Recall that these generics gained this exclusivity solely because Takeda had wrongfully listed the '584 Combo and '404 Insulin Patents in the Orange Book. If Teva (or any other company) were able to get a court declaration that the listing of those patents was unlawful, then the 180-day exclusivities that rested on those listings would be eliminated. Disincentives to pursue such a court order had the intended effect of diminishing the risk that the 180-day exclusivities would be eliminated.

128. *Fourth*, the arrangement restricted competition by prolonging the bottleneck presented by the 180-day exclusivity held by the first-filers. Because each of the first-wave generics had filed their Actos ANDAs before enactment of the 2003 MMA amendments, under the law before the amendments the first generic manufacturer(s) to file an ANDA with a Paragraph IV certification could not forfeit the 180-day exclusivity by failing to market the drug.

Therefore, the first generic drug manufacturer applicant could agree with the branded drug manufacturer to delay marketing the generic, while still safely retaining the 180-day exclusivity. By thus "parking" its 180-day exclusivity, the first filer could create a "bottleneck" that precluded *all* generic drug manufacturers from entering the market until 180-days after the first-filer entered.

129. The intended effect of Takeda's Exclusion Payment Agreements with each of Mylan, Ranbaxy, and Actavis was to delay entry into the market by them and all subsequent ANDA filers. Other generic drug manufacturer competitors had notified Takeda that they had filed ANDAs for generic of Aactos that contained a Paragraph IV certification as to the '584 Combo Patent and the '404 Insulin Patent. In each case, Takeda filed a patent infringement suit against the generic manufacturer alleging that the manufacturer's generic Actos product would directly infringe the '584 Combo Patent and '404 Insulin Patent, and indirectly infringe certain of the Actos Method-of-Use Patents, none of which actually claimed the pharmaceutical ingredient in Actos. Takeda filed the patent infringement cases against these potential generic drug manufacturer competitors without regard to the merits of the cases. Simply by filing these infringement casesTakeda obtained automatic exclusion of these ANDA filers from the market for thirty months.

130. In light of the prolonged bottleneck created by the Exclusion Payment Agreement with Mylan, Ranbaxy, and Actavis, the later generic filers each were, as a practical economic matter, required to fall in line with the protracted, delayed entry date for Actos generics.

131. *Fifth,* the arrangement restricted the competition by prolonging the bottleneck presented by the 180-day exclusivity held by Mylan for Acto*plus* met. As the first ANDA filer to submit a substantially complete ANDA with a Paragraph IV certification with respect to

Acto*plus* met, Mylan secured the Hatch-Waxman 180-day exclusivity. Although Congress had sought in the 2003 MMA amendments to reduce the incidence of drug manufacturers entering into Exclusion Payment Agreements to create "bottlenecks," unscrupulous manufacturers could still structure such agreements to create very substantial obstacles to entry by later-filing generics. Under the MMA, the generic first-filer retains its 180-day exclusivity if it enters into a consent judgment that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV certification were invalid or not infringed. In order to trigger forfeiture and gain access to the market, subsequent ANDA applicants are then forced to obtain a judgment that all patents for which the first filing generic manufacturer filed Paragraph IV certifications are invalid or not infringed.

132. Takeda and Mylan in fact "gamed the system" in just this way, entering into a voluntary dismissal without the requisite findings that would have resulted in a forfeiture of Mylan's 180-day exclusivity. Consequently, the Exclusion Payment Agreement constructed very substantial barriers to entry by later-filing generic drug manufacturers.

133. *Sixth* but by no means last, the arrangement restricted the competition by delaying the entry dates for generic Actos, thereby extending the $3 billion a year franchise for another year and a half.

K. Teva moves to add a counterclaim pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) against Takeda.

134. With the execution of the Exclusion Payment Agreement for Actos and Acto*plus* met in March 2010, and the consequent prolonged bottlenecks that also delayed entry by later-filing generic drug manufacturers, Takeda and its generic co-conspirators -- Mylan, Ranbaxy, and Actavis -- had tamed almost all of the threats that could unleash competitive rivalry and bring lower prices to consumers before the dates specified in the Exclusion Payment

Agreements. But one significant threat remained, so Takeda and its generic coconspirators worked together to neutralize the potential competitor and bring it into the conspirators' non-competition pact.

135. On March 30, 2010, Teva countered this development by filing a motion to amend its answer to add a counterclaim against Takeda based on Takeda's improper submission of patent information for the '584 Combo Patent and the '404 Insulin Patent describing the patents as drug product patents claiming Actos. As Teva stated in its proposed Amended Answer, Affirmative Defenses and Counterclaim:

> As a direct and proximate cause of Takeda's submission of false, misleading, and/or incorrect patent information to FDA . . . Teva is likely to suffer significant harm in the form of a substantial delay to the approval of Teva's Actos® ANDA. If Teva is required to file a Paragraph IV certification due to the incorrect listings of the '584 and the '404 Insulin Patents in the Orange Book, Takeda might file a new lawsuit triggering a 30-month stay of approval of Teva's Actos® ANDA. In addition, whether or not Takeda files such a lawsuit, Teva's ANDA could not be approved until after the expiration of any 180-day exclusivity period to which the first-filer(s) of ANDA(s) for generic versions of Actos® may be entitled. Either way, final approval of Teva's Actos® ANDA likely will be delayed substantially beyond the January 2011 date (the expiration of the '777 Compound Patent) on which Teva's ANDA otherwise likely would be approved.

Teva sought an order pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) requiring Takeda "to correct or delete the patent information Takeda submitted to FDA in reference to NDA 21-073 concerning the drug product claims in the '584 and '404 Patent[s] by submitting information to FDA clarifying that the drug product claims in those patents do not claim the drug product approved by NDA 21-073 and that those drug product claims do not form a basis upon which Takeda could reasonably assert a claim of patent infringement against an ANDA applicant for a generic version of Actos®." Had Teva succeeded on its counterclaim, Teva would not have

been subject to the 180-day bottleneck that Takeda and Mylan, Ranbaxy, and Actavis constructed and extended with their Exclusion Payment Agreements, and Teva could have entered the market with generic ACTOS as early as January 17, 2011.

136. Shortly after Teva filed its motion to add the counterclaim based on Takeda's improper listing of patent information for the '584 Combo Patent and '404 Insulin Patent, Takeda and Teva began serious settlement negotiations. At the parties' joint request, on April 14, 2010, the court adjourned the June 2010 trial date.

137. During the settlement negotiations, Takeda used "carrots and sticks." The sticks included the acceleration clauses that Takeda and its other generic drug manufacturer co-conspirators had incorporated in the Exclusion Payment Agreements for Actos. The acceleration clauses in the Exclusion Payment Agreement with each of Mylan, Ranbaxy, and Actavis provided that, in the event that any other manufacturer succeeded in entering the market with a generic Actos product before August 17, 2012, the licensed entry date for Mylan, Ranbaxy, and Actavis would be accelerated to the earlier date. The acceleration clauses thus ensured that no other generic drug manufacturer, no matter how much time and resources it spent in its litigation against Takeda, and no matter how successful the generic drug manufacturer was in the litigation, could enter the market before Mylan, Ranbaxy, and Actavis.

138. The purpose and effect of the acceleration clauses was to dramatically reduce Teva's incentive to try to enter the market before Mylan, Ranbaxy, and Actavis. Absent the acceleration clauses, Teva had a significant possibility of entering the market with generic Actos before August 17, 2012, thereby enjoying a substantial period as the only generic Actos product on the market. By eliminating this possibility, the acceleration clauses resulted in later generic entry in at least two ways: (i) the clauses directly reduced Teva's incentive to continue litigating

in order to gain entry before Mylan, Ranbaxy, and Actavis, and (ii) by eliminating the threat to Mylan's, Ranbaxy's, and Actavis' 180-day exclusivity, the clauses compensated them for delaying their entry into the market. In short, the acceleration clauses eliminated Teva's competitive threat to Mylan, Ranbaxy, and Actavis, in return for which they agreed to later entry.

139. While keeping most of the terms in their Exclusion Payment Agreements confidential, Mylan, Ranbaxy, and Actavis agreed that Takeda could advise Teva of the existence of the acceleration clauses. The purpose and effect of the disclosure was to dissuade Teva from entering the market before August 17, 2012.

140. The "carrots" that Takeda offered to Teva to give up the patent fight were the payments that the parties included in their unlawful Exclusion Payment Agreement, discussed below.

L. Takeda and Teva Execute an Exclusion Payment Agreement to Delay Teva's Generic Actos.

141. On December 22, 2010, Takeda and Teva entered into an Exclusion Payment Agreement pursuant to which Teva agreed to: (i) drop its challenges to Takeda's patents with respect to Actos; (ii) drop its counterclaim asserting that Takeda had submitted false and misleading patent information as to the '584 Combo Patent and '404 Insulin Patent; and (iii) stay out of the market with generic Actos until August 17, 2012.

142. As the *quid pro quo* for Teva's agreement to significantly delay competition, Takeda agreed to pay Teva substantial compensation. Takeda's payments to Teva under the Exclusion Payment Agreement took at least the following forms.

143. *First*, Takeda agreed that neither it nor its affiliates would launch an authorized generic version of Actos during Teva's first 180 days of marketing. This non-competition

pledge provided substantial compensation to Teva, which could expect higher unit sales, at a higher price, absent Takeda's authorized generic version of Actos in the market. The non-competition pledge was worth tens of millions of dollars and constitutes compensation to Teva.

144. *Second*, Takeda agreed that, with the exception of the licenses to which it had already agreed with Mylan, Ranbaxy, and Actavis, Takeda would not grant any other generic drug manufacturer a license to enter the market with generic Actos until 180 days after Teva entered the market. The no-license pledge was worth tens of millions of dollars and constitutes compensation to Teva.

145. *Third*, Takeda agreed that, in the event any other generic Actos entered the market before the time specified for Teva to enter the market, the licensed entry date for Teva would be accelerated correspondingly. As discussed in detail above, the purpose and effect of this acceleration clause was to deter any other generic drug manufacturer from entering before Teva's scheduled entry date.

146. *Fourth*, Takeda granted Teva a license to market generic Acto*plus* met under Takeda's NDA beginning on the date that Mylan first entered the market with its generic Acto*plus* met. Anticipating that they would succeed in enticing Teva to join the non-competition pact, Takeda and Mylan had agreed that Takeda could provide such a license to Teva with respect to Acto*plus* met, and Takeda and Mylan had included such a provision in their earlier agreement.

147. *Fifth*, Takeda agreed that neither it nor its affiliates would launch an authorized generic version of Acto*plus* met during Teva's first 180 days of marketing. This provided substantial compensation to Teva, which could expect higher unit sales, at a higher price, absent

Takeda's authorized generic version of Acto*plus* met in the market. The no-competition pledge was worth tens of millions of dollars and constitutes compensation to Teva.

148. *Sixth*, Takeda agreed that, with the exception of the licenses already granted to Mylan, Takeda would not grant any other generic drug manufacturer a license to enter the market with generic Acto*plus* met until 180 days after Teva entered the market. The no-license pledge was worth tens of millions of dollars and constitutes compensation to Teva.

149. *Seventh*, Takeda agreed that, in the event any other generic Acto*plus* met entered the market before the time specified for Teva to enter the market, the licensed entry date for Teva would be accelerated correspondingly. As discussed in detail above, the purpose and effect of this acceleration clause was to deter any other generic drug manufacturer from entering before Teva's scheduled entry date.

150. All of these benefits had substantial value to Teva, and are compensation that it could not have obtained even if it had litigated and won the patent case. These payments caused Teva to stay out of the market longer than it otherwise would have done. And Takeda made these payments to Teva in exchange for its agreeing to delay entry with its generic Actos. In short, Takeda made large, unjustified payments to Teva to delay entry of Teva's generic Actos product into the market.

M. The 2011 through 2014 acts in furtherance of the Exclusion Payment Agreement

151. From late January of 2011 (when they otherwise could have entered the ACtos market) until late August of 2012, each of Mylan, Ranbaxy, Actavis, and Teva abided by their agreements with Takeda – they did not launch generic products into those markets, and undertook whatever activities were required (with, for example, the FDA) so as to make sure they kept the promise to Takeda to stay out of the Actos market until late August of 2012.

Meanwhile, Takeda kept its promise and did not grant any licenses to other companies, all in accordance with its promises in the Exclusion Payment Agreement.

152. In or about the summer of 2012, Takeda worked closely with two of its co-conspirators – Teva and Ranbaxy – in order to implement the sweetheart authorized generic distributorships Takeda had granted them for Actos. In or about late August of 2012, Takeda and Teva, and also Takeda and Ranbaxy, launched authorized generics of Actos. Neither Teva nor Ranbaxy launched their own, ANDA-approved generic at this time. Takeda also kept its commitment not to launch an independent (market rate) authorized generic.

153. For at least two years, and certainly into 2014, Takeda continued to pay both Teva and Ranbaxy through the sweetheart, authorized distributorships. The distributorship was so valuable to Teva that Teva did not press for approval of its own ANDA-approved generic for many months.

154. In or about the summer of 2012, Takeda also worked closely with Teva in order to implement the sweetheart authorized generic distributorship Takeda had granted it for Acto*plus* met. In or about late August of 2012, Takeda and Teva launched an authorized generic of Acto*plus* met. Teva did not launch its own, ANDA-approved generic at this time. Takeda also kept its commitment not to launch an independent (market rate) authorized generic of Acto*plus* met.

155. For at least two years, and certainly into 2014, Takeda continued to pay Teva through the sweetheart, Acto*plus* met authorized distributorship. The distributorship was so valuable to Teva that Teva did not press for approval of its own ANDA-approved generic for many months.

156. The Exclusion Payment Agreement had its intended impact on the Actos market. First, generics were delayed from late January until late August of 2012, during which monthly sales were about $200 million. In effect, the agreement protected Takeda from generic competition during which retails sales totaled about $3.6 billion. Second, the agreement's plan to protect high sales for a few generics during the first six months of entry worked. During this period, only the conspiring generics were able to get into the Actios market,, at which point they shared sales of about a $100 million per month market. Upon the entry of other generics, the market size would drop to about $60 million per month.

157. Third, the agreement's plan to keep prices relatively high for the first six months of exclusivity also worked. While in the first six months the average retail price was in the $240 to $250 per prescription range, post-exclusivity the average retail price dropped to about $165 per prescription or lower. A competitive market for Actos would have yielded about $60 million a month shared amongst many competitors; it would not have been the $200 million a month Takeda enjoyed by itself for 18 months, nor the $100 million a month the co-conspiring oligopoly of generics enjoyed for the first six months of (unlawfully produced) exclusivity.

VII. MARKET POWER AND DEFINITION

158. Takeda wrongfully acquired and used market power over the market for Actos.

159. At all relevant times, Takeda had market power over Actos and its generic equivalents because it had the power to maintain the price of Actos at supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable. This market power may be shown directly, and therefore no relevant market needs to be defined.

160. Actos is not reasonably interchangeable with any products other than AB-rated generic versions of Actos.

161. A small, but significant, non-transitory price increase above the competitive level for Actos by Takeda would not have caused a loss of sales sufficient to make the price increase unprofitable.

162. Actos does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Actos. Other oral Type 2 diabetes medicines are not AB-rated to Actos, cannot be automatically substituted for Actos by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Actos, and thus, are not economic substitutes for Actos.

163. Actos is part of the Type 2 diabetes drug class called thiazolidinediones. Thiazolidinediones, like a few other antidiabetic classes of drugs, are often referred to as "insulin sensitivity enhancers" due to their ability to decrease the body's resistance to insulin. Unique to thiazolidinediones, however, is that they increase certain levels of proteins – those that are more sensitive to insulin – and thus are the primary means by which a patient's blood sugar levels may be lowered. Due to their differing effect within the body, thiazolidinediones are significantly unique in their efficacy, safety, and side effect profile. These attributes play a critical role in doctors' selection of the most appropriate antidiabetic for a particular patient.

164. Due to, among other reasons, doctors' perception of Actos' lower association with heart failure, death, and liver toxicity, Actos is significantly differentiated from other drugs in the thiazolidinedione class. For these and other clinical reasons, substantial numbers of doctors prefer Actos to other thiazolidinedione drugs (e.g., Avandia (rosiglitazone)). For example, according to some studies patients aged 65 and older who take Avandia (rosiglitazone) have a higher rate of death and a greater risk of heart failure when compared with similar patients taking Actos.

165. Functional similarities between Actos and non-Actos thiazolidinedione products are insufficient to permit inclusion of those other thiazolidinedione products in the relevant market with Actos. To be an economic substitute for antitrust purposes, a functionally similar product must also exert sufficient pressure on the prices and sales of another product, so that the price of that product cannot be maintained above levels that would be maintained in a competitive market. No other thiazolidinedione product (except for AB-rated generic Actos) will take away sufficient sales from Actos to prevent Takeda from raising or maintaining the price of Actos above levels that would prevail in a competitive market.

166. At all relevant times, the existence of other products designed to treat adults with Type 2 diabetes did not significantly constrain Takeda's pricing of Actos. At all relevant times, Takeda's price for Actos was at least 60% above its marginal cost of production and at least 40% above its marginal cost including marketing costs. Takeda never lowered the price of Actos in response to the pricing of other branded treatments for Type 2 diabetes (or the generic versions of such medications).

167. Takeda needed to control only Actos and its AB-rated generic equivalents, and no other products, to profitably maintain the price of Actos at supracompetitive levels. Only the market entry of a competing, AB-rated generic version of Actos would have rendered Takeda unable to profitably maintain supracompetitive prices for Actos.

168. Takeda knew that entry of a generic version of Actos would be a uniquely significant market event. Takeda predicted that, unlike the entry of other branded treatments for Type 2 diabetes (or the generic versions of such medications), entry of generic Actos would take substantial unit sales from Takeda. For example, Actos did not lose substantial sales when generic versions of other branded Type 2 diabetes drugs entered the market at low prices. But

Takeda predicted that entry of generic Actos would immediately cause branded Actos to lose well more than half of its unit sales. Likewise, Mylan, Ranbaxy, Actavis, and Teva estimated that their generic versions of Actos would take essentially all of their sales away from branded Actos and few, if any, sales from other branded Type 2 diabetes drugs (or generic versions of such medications).

169. Takeda, Mylan, Ranbaxy, Actavis, and Teva predicted that the competitive impact of generic Actos products would be substantial. Among other things, Defendants predicted that the availability of generic Actos would deliver well more than a billion dollars of savings to consumers.

170. At all relevant times, Takeda sold Actos at prices well in excess of its marginal costs and the Actos competitive price, and enjoyed the resulting high profit margins and corresponding financial benefits—to the financial detriment of Plaintiff and the Actos class members.

171. Takeda had, and exercised, the power to exclude and restrict competition to Actos and its AB-rated bioequivalents.

172. Takeda, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections, as well as the high cost of entry and expansion.

173. To the extent Plaintiff is legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant product market is oral pioglitazone hydrochloride for the treatment of adults with Type 2 diabetes (*i.e.*, Actos and its AB-rated generic equivalents). At all relevant times, Takeda profitably maintained the price of pioglitazone hydrochloride well above competitive levels.

174. The relevant geographic market is the United States and its territories.

175. At all relevant times prior to generic entry, Takeda's market share in the relevant geographic market was 100%, confirming its monopoly power. Takeda continued to possess substantial market share and market power after generic entry.

VIII. MARKET EFFECTS AND CLASS DAMAGES

176. But for the anticompetitive conduct alleged above, generic competition for Actos would have begun as early as January 17, 2011.

177. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Actos from generic competition. Defendants' unlawful conduct was designed to, and did, discourage rather than encourage competition on the merits. Such conduct was undertaken for the anticompetitive purpose of forestalling generic competition.

178. Defendants' exclusionary conduct delayed generic competition, and unlawfully allowed Takeda to sell its branded drug products free from competition. But for this wrongful conduct, one or more generic competitor would have begun marketing AB-rated generic versions of these drugs much sooner than they actually were marketed.

179. Other generic manufacturers seeking to sell AB-rated generic versions of Actos, including Mylan, Ranbaxy, Actavis, and Teva all had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products, and at least several of these generic manufacturers would have been ready, willing and able to effectuate earlier launches of their generic versions, were it not for Defendants' illegal and unlawful acts and conspiracy.

180. Defendants' unlawful actions and anticompetitive conduct allowed Takeda to maintain a monopoly and exclude competition in the markets for Actos, and their generic

equivalents, and to maintain supracompetitive prices for Actos to the detriment of Plaintiff and all other direct purchaser class members. Defendants' anticompetitive conduct delayed and impaired generic competition and unlawfully enabled Takeda to sell Actos without timely generic competition.

181. Typically, generic drugs are initially priced significantly below the corresponding branded drug to which they are AB-rated. As a result, upon generic entry, direct purchasers rapidly substitute generic versions of a branded drug for some or all of their purchases. As more generic drug manufacturers enter the market, prices for generic versions of a branded drug predictably plunge even further due to competition between the generic drug manufacturers, and, correspondingly, the branded drug loses even more market share to the generics.

182. This price competition enables all purchasers of the drug to (i) purchase generic versions of a drug at substantially lower prices, (ii) purchase generic equivalents of the drug at a lower price, sooner, and (iii) purchase the branded drug at a reduced price. Consequently, branded drug manufacturers have a keen financial interest in delaying and impairing the onset of generic drug competition, which, in turn causes purchasers to experience substantial increases in costs.

183. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets by the Defendants' anticompetitive conduct, direct purchasers, such as Plaintiff and class members, would have paid less for these drugs by (i) receiving discounts on their remaining brand purchases of Actos; (ii) substituting less-expensive AB-rated generic Actos for the more expensive branded Actos, and/or (iii) purchasing generic Actos at lower prices sooner.

184. Moreover, due to Defendants' anticompetitive conduct, other generic drug manufacturers were discouraged from and/or delayed in (i) developing and marketing their own generic versions of Actos and/or (ii) challenging the validity or infringement of Takeda's patents in court.

185. At all relevant times during the class period, Plaintiff and the direct purchaser class members directly purchased substantial amounts of Actos. As a direct and proximate result of Defendants' illegal conduct, Plaintiff and the direct purchaser class members were compelled to pay, and did pay, artificially inflated prices for Actos and their generic equivalents.

186. As a direct and proximate result of Defendants' unlawful anticompetitive scheme and wrongful conduct, Plaintiff and the direct purchaser class members have sustained (and will continue to sustain) substantial losses and damage to their business and property in the form of overcharges they paid for Actos and its AB-rated generic equivalents, the exact amount of which will be proven at trial.

187. Defendants' unlawful conduct deprived Plaintiff and the direct purchaser class members of the benefits of competition that the antitrust laws were designed to ensure.

IX. ANTITRUST IMPACT AND INTERSTATE COMMERCE

188. During the relevant period, Plaintiff and members of the direct purchaser class purchased substantial amounts of Actos directly from Takeda and/or purchased substantial amounts of generic versions of Actos from generic manufacturers.

189. As a result of Defendants' illegal conduct, Plaintiff and members of the direct purchaser class were compelled to pay, and did pay, artificially inflated prices for their drug requirements on these purchases. Those prices were substantially greater than the prices that Plaintiff and members of the direct purchaser class would have paid absent the illegal conduct alleged herein, because: (1) the price of Actos was artificially inflated by Defendants' illegal

conduct; (2) Plaintiff and direct purchaser class members were deprived of the opportunity to purchase lower-priced generic Actos sooner; and/or (3) the price of generic Actos was artificially inflated by Defendants' illegal conduct.

190. As a consequence, Plaintiff and members of the direct purchaser class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial

191. At all relevant times, Takeda manufactured, promoted, distributed, and sold substantial amounts of Actos in a continuous and uninterrupted flow of commerce across state and national lines throughout the United States.

192. At all material times, Defendants transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Actos and their generic equivalents.

193. In furtherance of their efforts to monopolize and restrain competition, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Defendants' activities were within the flow of, and have substantially affected (and will continue to substantially effect), interstate commerce.

X. CLAIMS FOR RELIEF

COUNT ONE: VIOLATION OF 15 U.S.C. § 2: MONOPOLIZATION (AGAINST THE TAKEDA DEFENDANTS)

194. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

195. At all relevant times, Takeda possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Takeda possessed the power to control prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

196. Through its overarching anticompetitive scheme, as alleged above, Takeda willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and thereby injured Plaintiff and the class.

197. It was Takeda's conscious object to further its dominance in the relevant market by and through the overarching anticompetitive scheme.

198. The natural and probable consequence of Takeda's overarching anticompetitive scheme, which was intended by it and plainly foreseeable to it, was to control prices and exclude competition in the relevant market.

199. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Takeda would succeed in and achieve its goal of maintaining monopoly power in the relevant market.

200. Takeda's scheme harmed competition.

201. There is and was no cognizable, non-pretextual procompetitive justification for Takeda's actions comprising the anticompetitive scheme that outweighs the scheme's harmful effects. Even if there were some conceivable such justification that Takeda were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

202. As a direct and proximate result of Takeda's illegal and monopolistic conduct, as alleged herein, Plaintiff and the class were harmed.

COUNT TWO: VIOLATION OF 15 U.S.C. § 2: CONSPIRACY TO MONOPOLIZE (AGAINST ALL DEFENDANTS)

203. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

204. Through the overarching anticompetitive scheme, detailed above, including the Exclusion Payment Agreements with Mylan, Ranbaxy, Actavis, and Teva, Defendants conspired to maintain Takeda's monopoly power in the relevant market in order to block and delay market entry of pioglitazone hydrochloride, *i.e.*, AB-rated generic versions of Actos. The unlawful Exclusion Payment Agreements allocated all sales of pioglitazone hydrochloride in the United States to Takeda; delayed sales of generic Actos; and fixed the price at which Plaintiffs and members of the Class would pay for pioglitazone hydrochloride at both the higher, branded price, and at the higher generic price (resulting from the delay of generic entry); delayed and allocated all sales of generic Actos in the United States to the Generic Defendants.

205. The goal, purpose and/or effect of the anticompetitive scheme, detailed above, including the Exclusion Payment Agreements was to maintain and extend Takeda's monopoly power in the United States market for pioglitazone hydrochloride in violation of 15 U.S.C. § 2. The Exclusion Payment Agreement prevented and/or delayed generic competition to Actos and enabled Takeda to continue charging supracompetitive prices for Actos without a substantial loss of sales.

206. Defendants knowingly and intentionally conspired to maintain and enhance Takeda's monopoly power in the relevant market.

207. Each Defendant committed at least one over act in furtherance of the conspiracy.

208. Defendants specifically intended their conspiracy, including its Exclusion Payment Agreements, to extend Takeda's monopoly power in the relevant market, and directly and proximately injured Plaintiff and class members thereby.

COUNT THREE: VIOLATION OF NEW YORK'S DONNELLY ACT (AGAINST ALL DEFENDANTS)

209. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

210. The aforementioned acts and practices by Defendants were and are in violation of New York's Donnelly Act, N.Y. Gen. Bus. Law § 340, *et seq.*

211. It is appropriate to apply New York antitrust law to direct purchases of Actos in all fifty states because the illegal conspiracy, overt acts in furtherance thereof, and other anticompetitive conduct and overcharges occurred in New York.

212. Defendants reside and/or conduct significant business in New York. In fact, Takeda's U.S.-based operations are headquartered in New York City.

213. Defendants' in-state conduct caused substantial out-of-state injuries to Plaintiffs and the proposed nationwide class of pioglitazone hydrochloride purchasers and had a significant impact on the intrastate commerce of New York. By way of example, many Class members paid to Defendants prices for Actos that were artificially inflated by Defendants' unlawful actions in New York.

214. As a direct and proximate result, Plaintiff and Class members have been injured in their property in that they had to pay artificially high prices for pioglitazone hydrochloride.

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the Class, prays that the Court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the class, and declare CCI as a named representative of the class;

B. Conduct expedited discovery proceedings leading to a prompt trial on the merits before a jury on all claims and defenses;

C. Enter joint and several judgments against the Defendants and in favor of CCI and the class;

D. Award the class damages (*i.e.*, three times overcharges) in an amount to be determined at trial, plus interest in accordance with law;

E. Award CCI and the class their costs of suit, including reasonable attorneys' fees as provided by law; and

F. Award such further and additional relief as is necessary to correct for the anticompetitive market effects caused by the Defendants' unlawful conduct, as the Court may deem just and proper under the circumstances.

XII. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed class, demands a trial by jury on all issues so triable.

Dated: May 4, 2015.

Respectfully submitted,

By: _____

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